REMARKS

Claims 24-26, 29-31, 33-35, and 48-53 are pending in this application. Claims 27-28, 32, and the withdrawn claims 36-47 are canceled without prejudice or disclaimer. Applicants reserve the right to pursue the canceled claims in one or more divisional and/or continuation applications. Claims 24, 26, 29, 30, 31, 33, and 35 are amended for clarity, to correct dependencies and informalities, as discussed below. Claims 48-53 are new and are fully supported by the specification, as explained herein.

Claims 24 and 35 have been amended for clarity, without prejudice or disclaimer, to delete reference to detection of individuals that have been infected with *Neisseria gonorrhoeae*.

Claim 24 has been amended to recite that the biological sample is subjected to nucleic acid sequence amplification using one or more oligonucleotides to produce an amplification product comprising a nucleotide sequence within residues 681-972 of SEQ ID NO:10. Nucleic acid sequence amplification-based analysis is supported by original claim 4. The nucleotide sequence within residues 681-812 of SEQ ID NO: 10 is the fragment of porA that is amplified by oligonucleotide primers SEQ ID NOS:1 and 2, as deduced from the sequence provided in FIG. 1 and the sequence positions listed in Table 2.

The functional language in claim 24, "wherein said one or more oligonucleotides are not capable of hybridizing to a porA nucleic acid of *Neisseria meningitidis* sufficiently to enable detection of said porA nucleic acid of *Neisseria meningitidis* if present in said biological sample" is deleted for clarity.

New independent claim 48 has been added which recites detecting a nucleotide sequence of an isolated porA nucleic acid of *Neisseria gonorrhoeae*, if present in a biological sample obtained from said individual, a presence of said nucleotide sequence indicating that said individual is infected with *Neisseria gonorrhoeae*, wherein said nucleotide sequence is of an amplification product obtainable by nucleic acid sequence amplification using PCR primers having a nucleotide sequence according to SEQ ID

NO:1 and SEQ ID NO:2. The subject matter of claim 48 is supported by original claims 1, 4 and 6. New dependent claims 49 and 50 mirror current dependent claims 33 and 34. New dependent claims 51-53 refer to detection of the amplification product by nucleotide sequencing, as supported by page 12, lines 5-7 of the original specification.

As clarified above, amendments to the claims and the new claims are fully supported by the specification and no new matter has been introduced. The Office Action is discussed below:

Priority:

On page 2 of the Office Action, the examiner acknowledges that this application's foreign priority is based on the application filed in Australia on April 8, 2004. Although applicants have amended the application on October 5, 2006 with the priority claim, the filing date of PCT/AU05/00500 (April 5, 2005) has been used by the examiner for the determination of the availability of art.

The examiner has rejected the priority claim based on AU2004901890 on the basis that a certified copy of AU2004901890 was not provided to the examiner. In response, applicants submit that this application is a national stage application derived from PCT application PCT/AU2005/000500. Under PCT Rule 17.1 a certified copy of AU2004901890 was forwarded by the Australian Receiving Office to WIPO. Generally, this is all that is required to satisfy priority claiming requirements under the PCT. Applicants therefore do not believe that the examiner was correct in asserting the invalidity of the priority claim.

However, in order to advance the prosecution, applicants attach herewith a certified copy of AU2004901890 and trust that the examiner now considers the priority date of April 8, 2004 as the relevant date for the determination of the availability of art.

Sequence Compliance:

On pages 2-3 of the Office Action, the examiner alleges that the application fails to comply with the requirements and cites a "Notice To Comply" with requirements for

patent applications containing nucleotide sequence and/or amino acid sequence disclosures. Specifically, the examiner asserts that page 27 contains sequences without the requisite sequence identifiers. Applicants have filed the sequence listing and complied with the requirements by filing an amendment to the specification on August 30, 2007 (see pages 2-3 of the amendment), wherein Table 1 of page 27 of the specification is amended to include the requisite sequence identifiers SEQ ID NOs. 1-4. The amended Table 1 clearly identified "SEQ ID NOS 1-4, respectively in order of appearance". The amendment also identified sequences listed on Figure 1 of the specification. Accordingly, applicants received the US PTO's Notice of Acceptance dated February 11, 2009.

However, for additional clarity, applicants herewith submit another amendment to Table 1 of page 27 of the specification to include the sequence identifiers SEQ ID NOs. 1-4 for each sequence in order.

Written Description Rejection:

On pages 3-5 of the Office Action, the examiner rejects claims 24-29 and 31-34 under 35 U.S.C. 112, first paragraph, allegedly for failing to comply with the written description requirement.

According to the examiner, the specification discloses SEQ ID NO:1 and 2 that correspond to PCR primers specific for the porA gene of *Neisseria gonorrhoeae* but no other Neisserial species. The examiner agrees that SEQ ID NO:1 and 2 meet the written description requirement, but contends that the claims are drawn to any and all PCR primers that hybridize to the porA gene of *Neisseria gonorrhoeae* but not *Neisseria meningitidis* (refers to claims 25, 27-35) or any other Neisserial species (refers to claim 26). The examiner believes that none of these sequences meet the written description provision and the specification provides insufficient written description to support the genus encompassed by the claim.

Applicants respectfully disagree with the examiner and submit that one skilled in the art would be able practice the claimed invention based on the disclosure. However,

without acquiescing in the rejection and in order to expedite the prosecution, applicants amend claim 24 to recite that the detected amplification product comprises residues 681-812 of SEQ ID NO: 10, which is the region of porA amplified by SEQ ID NOS: 1 and 2. While amended claim 24 does not recite that the oligonucleotide primers must be SEQ ID NOS: 1 and 2, applicants submit that the group of primers that are encompassed by claim 24 is relatively small and hence SEQ ID NOS: 1 and 2 provide an adequate number of species of the class of primers that can amplify this region.

Applicants note that new claim 48 recites that the detected nucleotide sequence is obtainable by amplification by primers comprising the nucleotide sequences of SEQ ID NOS: 1 and 2. While claim 48 does not recite that the sequence amplification must be performed using SEQ ID NOS: 1 and 2, the group of primers that are encompassed by claim 48 is relatively small and SEQ ID NOS: 1 and 2 provide an adequate number of species of the class of primers that can amplify this region.

Therefore, it is clear that the specification provides an adequate written description supporting the amended claims 24-26, 29-31 and 33-35, and the new claims 48-53. Accordingly, withdrawal of the written description rejection is solicited.

Enablement Rejection:

On pages 5-6 of the Office Action, the examiner also rejects claims 24-35 under 35 U.S.C. 112, first paragraph, and asserts that the specification, while being enabling for methods of determining whether an individual is actively infected with *Neisseria gonorrhoeae* utilizing the PCR primers consisting of the sequences of SEQ ID NO: 1 and 2, does not reasonably provide enablement for methods of determining whether an individual has previously been infected with *Neisseria gonorrhoeae.*

Again, applicants respectfully disagree with the examiner and refer to above clarification that one skilled in the art would be able practice the claimed invention based on the disclosure. Primarily, applicants understand the examiner to have identified the language "has been infected with *Neisseria gonorrhoeae*" as rendering the former claims as lacking enablement.

Given that this language has been deleted without prejudice from the claims in the interests of progressing allowance of the claims, applicants trust this rejection is now moot.

Applicants also submit the following:

Claim 24 now recites that the detected amplification product comprises residues 681-812 of SEQ ID NO: 10, which is the region of porA amplified by SEQ ID NOS: 1 and 2. New Claim 48 recites that the detected nucleotide sequence is obtainable by amplification by primers comprising the nucleotide sequences of SEQ ID NOS: 1 and 2. While amended claim 24 and new claim 48 do not recite that the oligonucleotide primers must be SEQ ID NOS: 1 and 2, applicants submit that a person skilled in the art would readily be able to design alternative primers based on SEQ ID NOS: 1 and 2 and/or using other flanking sequences surrounding residues 681- 812 of SEQ ID NO: 10 (see page 10 lines 6-11 as filed) that would appropriately anneal to the target sequence to allow amplification of this region (see page 11 lines 10-28 and reference to primer design in CURRENT PROTOCOLS IN MOLECULAR BIOLOGY Chapter 15). Applicants also submit that this is not a difficult or unpredictable art when a skilled person possesses the appropriate *Neisseria gonorrhoeae* porA target sequence and examples of primers (SEQ ID NOS:1 and 2) that work.

In view of the above clarifications and amendments to the claims, applicants request withdrawal of the enablement rejection.

Indefiniteness Rejection:

On pages 6-7 of the Office Action, the examiner rejects claims 30, 32-33 and 35 under 35 U.S.C. 112, second paragraph, allegedly as being indefinite.

Regarding claim 30, the examiner asserts that the claim is rendered vague and indefinite by the use of the phrase "having a nucleotide sequence..." It is unclear to the examiner whether this is meant to convey open or closed claim language, and suggested that either "comprising" or "consisting of be used. Applicants amend the claim to recite the term "comprising" as suggested by the examiner.

The examiner also asserts that claims 32-33 are rendered vague and indefinite by the use of the phrase "has a nucleotide sequence...." It is unclear to the examiner whether this is meant to convey open or closed claim language, and suggested that either "comprising" or "consisting of" be used. Claim 32 has been canceled without prejudice or disclaimer. Applicants amend claim 33 to recite the term "comprising" as suggested by the examiner.

Also, regarding claim 35, the examiner asserts that the claim is rendered vague and indefinite by the use of the phrase "nucleotide sequences according to SEQ ID NO...." It is unclear to the examiner whether this is meant to convey open or closed claim language, and suggested that either "comprising" or "consisting of" be used. In response, as suggested by the examiner, applicants amend the claim to recite the term "comprising" and amend the claim steps (i) and (ii) to recite "comprising nucleotide sequences selected from the group consisting of".

In view of the above discussed amendments to the claims, applicants request withdrawal of the indefiniteness rejection.

Anticipation Rejection:

On page 7 of the Office Action, the examiner rejects claims 24-35 under 35 U.S.C. 102(b) allegedly as being anticipated by Whiley *et al.* (European Journal of Microbial Infectious Diseases, 2004, Vol. 23 pages 705-710).

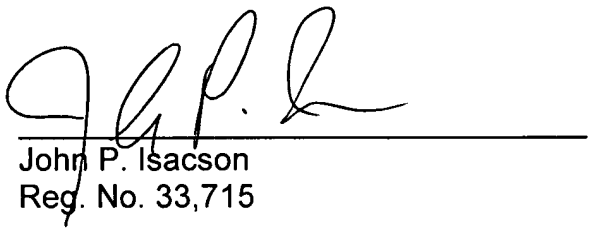
Whiley was published as an electronic publication on July 10, 2004, which is after the April 8, 2004 priority date of the priority document AU2004901890. Furthermore, Whiley was published less than 12 months before the PCT filing date of April 6 2005, which means that the citation of Whiley as a prior art under section 102(b) was improper.

Further, as noted above under Priority, since a certified copy of the priority document AU 2004901890 application (filed in Australia on April 8, 2004) has been provided, Whiley (as published on July 10, 2004) is not a prior art to the instant application. Accordingly, the anticipation rejection should be withdrawn.

REMARKS

Applicants submit that claims 24-26, 29-31, 33-35, and 48-53 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 434-1610 should there be any questions.

Respectfully submitted,



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Date

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